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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,902	06/19/2006	David Morton	478.1074	1653

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EXAMINER	
KENNEDY, NICOLETTA	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,902	MORTON ET AL.	
	Examiner	Art Unit	
	Nicoletta Kennedy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/7/06, 3/7/06, 6/19/06.

DETAILED ACTION

Status of Claims

Claims 1-29 are currently pending. Claims 16-24 are withdrawn as drawn to a non-elected group.

Priority

This application, filed March 7, 2006, is a national stage entry of PCT/GB04/03938 filed September 15, 2004, and claims foreign priority to United Kingdom applications 0409133.6 and 0321608.2, filed April 23, 2004 and September 15, 2003 respectively. Applicants have provided certified copies of the United Kingdom applications.

Election/Restrictions

1. Applicant's election without traverse of the restriction requirement in the reply filed on August 14, 2009 is acknowledged.

2. Claims 16-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 14, 2009.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-5, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Snyder et al. (US 2002/0071871).

Regarding claim 1, Snyder et al. teach a method of making dry particles for pulmonary administration (abstract). Snyder et al. further teach that powders for pulmonary drug administration have been made by spray drying (para. 0004). The spray drying method comprises drying a pharmaceutical active agent wherein the droplets move at a controlled velocity (paras. 0012, 0038, and 0054).

Regarding claim 3, Snyder et al. teach that the spray drier comprises an ultrasonic nebulizer (pars. 0045 and figure 8).

Regarding claims 4 and 5, the output of the single ultrasonic nebulizer unit is 20 ml/min (para. 0074 and Table 2).

Regarding claims 8-10, the particles may further comprise leucine as an exc ipient or dispersing agent (paras. 0067 and 0069).

Therefore, Snyder et al. anticipates claims 1, 3-5, and 8-10.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. (US 2002/0071871) in view of Wiedmann et al. (Pharm. Dev. & Tech.).

Regarding claim 1, from which claim 2 depends, Snyder et al. teach a method of making dry particles for pulmonary administration (abstract). Snyder et al. further teach that powders for pulmonary drug administration have been made by spray drying (para. 0004). The spray drying method comprises drying a pharmaceutical active agent wherein the droplets move at a controlled velocity (paras. 0012, 0038, and 0054).

However, Snyder et al. fail to teach the velocity of the droplets at 5mm from their point of generation. Wiedmann et al. cure this deficiency. Wiedmann et al. teach an ultrasonic spray system for ultimate use in respiratory drug delivery (abstract). The median aerodynamic particle diameters ranged from 1 to over 6 microns (p. 86).

Wiedmann et al. explain that the ultrasonic nebulizer is regarded as a soft, low-velocity spray wherein the particles are emitted with an estimated linear velocity of 21cm/s (p. 88). If the initial linear velocity is 21cm/s or 0.21m/s, then the velocity at 5mm from point of generation is less than 20m/s.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have combined the teachings of Snyder et al. with those of Wiedmann et al. One of ordinary skill would have been motivated to use an ultrasonic nebulizer to deliver the medicament at a low velocity because ultrasonic nebulizers allow smaller particle size, resulting in deeper penetration of the medicament into the lungs.

9. Claims 1, 6-7 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. (US 2002/0071871) in view of Kodas et al. (US 6,051,257).

Regarding claim 1, from which claims 6-7 and 26 depend, Snyder et al. teach a method of making dry particles for pulmonary administration (abstract). Snyder et al. further teach that powders for pulmonary drug administration have been made by spray drying (para. 0004). The spray drying method comprises drying a pharmaceutical active agent wherein the droplets move at a controlled velocity (paras. 0012, 0038, and 0054).

Regarding claims 6 and 7, Snyder et al. fail to teach. Kodas et al. cure this deficiency. Kodas et al. teach a method of making dry powder particles wherein the particle size is 2 microns and that 90% of the resulting dried particles have a size of less than 4 micrometers (column 18, lines 4-19). Additionally, Kodas et al. teach that 90% of the particles are preferably less than 3 micrometers (column 18, lines 17-19). Further,

the particles may have an average size Kodas et al. teach that the density of the particles is slightly greater than 1g/cc (column 18, line 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have combined the teachings of Snyder et al. with those of Kodas et al. One of ordinary skill would have been motivated to do so because Kodas et al. teaches that for dry powder inhalers, it in desirable to have an aerodynamic diameter of about 2 micrometers, wherein an aerodynamic diameter is defined as a particle which behaves aerodynamically like a spherical particle with a density of 1g/cc (Kodas et al., column 17, lines 60-65).

10. Claims 1, 8 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. (US 2002/0071871) in view of Kuo et al. (US 6,518,239).

Regarding claim 1, from which claims 8 and 11-15 depend, Snyder et al. teach a method of making dry particles for pulmonary administration (abstract). Snyder et al. further teach that powders for pulmonary drug administration have been made by spray drying (para. 0004). The spray drying method comprises drying a pharmaceutical active agent wherein the droplets move at a controlled velocity (paras. 0012, 0038, and 0054).

Regarding claim 8, Snyder et al. teach that the particles may further comprise leucine as an excipient or dispersing agent (paras. 0067 and 0069).

However, Snyder et al. fail to teach whether the blend of active agent and leucine as force control agent is in a solution or suspension as taught by Applicants in claims 11-14. Kuo et al. cure this deficiency.

Regarding claims 11-13, Kuo et al. teach a method for increasing dispersibility of an active-agent containing formulation for administration to the lung (abstract). The solutions are preferably prepared by spray-drying (column 11, lines 12-13). Kuo et al. teach that the compositions comprising an active ingredient and excipient are preferably solutions but may also be suspensions (column 11, lines 1-7).

Regarding claim 14, Kuo et al. teach a method for increasing dispersibility of an active-agent containing formulation for administration to the lung (abstract). Leucine may be used as an excipient and is preferably present from 1 to about 60% by weight (column 9, lines 49-53). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range lies inside the range disclosed by the prior art and is therefore prima facie obvious.

Regarding claim 15, Kuo et al. teach that the spray dried particles may be spray freeze dried (column 12, lines 23-24). Applicants, in the instant specification, state that the moisture content may be adjusted by freeze drying the particles (p. 44).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have combined the teachings of Snyder et al. with those of Kuo et al. One of ordinary skill would have been motivated to use an excipient from 1 to about 60% by weight and adjust the moisture content of the composition to maximize the stability of the composition and ease of delivery.

11. Claims 1, 25, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. (US 2002/0071871) in view of Tarara et al. (US 6,565,885).

Regarding claim 1, from which claims 25 and 27-29 depend, Snyder et al. teach a method of making dry particles for pulmonary administration (abstract). Snyder et al. further teach that powders for pulmonary drug administration have been made by spray drying (para. 0004). The spray drying method comprises drying a pharmaceutical active agent wherein the droplets move at a controlled velocity (paras. 0012, 0038, and 0054).

Regarding claims 25 and 27-29, Snyder et al. fail to teach the fine particle fraction. However, Tarara et al. cure this deficiency. Tarara et al. teach that a dry powder composition for use in a nebulizer for pulmonary delivery has a fine particle fraction of greater than about 40%, 50%, 60% or 70% by weight (column 27, lines 61-64).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have combined the teachings of Snyder et al. with those of Tarara et al. One of ordinary skill would have been motivated to have a fine particle fraction of greater than 40%, 50%, 60&, 70% because the increasing the fine particle

fraction increases the amount of active medicament delivered per actuation from the nebulizer (Tarara et al., column 27, lines 51-55).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicoletta Kennedy/

Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611